

US3412184 (Prod: New Horizons Clinical Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:22:31

All time stamps listed in this document are displayed in GMT

US3412184

Form: Participant Creation

Generated On: 26 Nov 2020 09:22:31

[Participant ID](#)

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[mRNA-1273-P301 Completion Guidelines](#)

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☒
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:22:31

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:22:31

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

Condition	OSTEOARTHRITIS BI-LATERAL KNEES
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:37 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 09:37
Height (<i>xxx.x</i>)	165.6 cm
Weight (<i>xxx.x</i>)	88.1 kg
BMI (<i>xxx.x</i>)	32.12590 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Is the participant of childbearing potential?	Yes ☐
	No ☒
If No, what is the reason?	Surgically sterile ☐
	Post-menopausal ☒
	Partner medically sterile ☐
	Not reached age of Menarche ☐
	Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>)	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 1996
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☒ No ☐

Specify

HAS HEALTH CARE WORKER
COME TO HOUSE FOR
HUSBAND

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	True
Specify	LIVES IN (b) (6)

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 185180

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☐
 >=65 years ☒

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	09:37 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 09:37
Temperature (xxx.x)	36.3 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	11:06 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 11:06
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	10 AUG 2020
What was the treatment time? (00:00-23:59)	10:35 (24 HR)
Treatment Date and Time (derived)	10 AUG 2020 10:35
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	10 AUG 2020
Collection time (<i>00:00-23:59</i>)	10:00 (24 HR)
Collection date and time (derived)	10 AUG 2020 10:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:22:31

Collection date (<i>dd MMM yyyy</i>)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:09	10 AUG 2020 10:09
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

Was any **MEDICATION TAKEN today for pain or fever?**

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

10 AUG 2020 11:07

PC Open Date & Time

10 AUG 2020 10:55

PC Close Date & Time

10 AUG 2020 13:25

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp 10 AUG 2020 21:14

PC Open Date & Time 10 AUG 2020 14:20

PC Close Date & Time 11 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

12 AUG 2020 09:40

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE in °F**

Was any **MEDICATION TAKEN today for pain or fever?** Yes ☐
No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

13 AUG 2020 12:40

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

14 AUG 2020 20:49

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

15 AUG 2020 23:48

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.6 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp 16 AUG 2020 22:30

PC Open Date & Time 16 AUG 2020 12:00

PC Close Date & Time 17 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 11:12

PC Open Date & Time

10 AUG 2020 10:55

PC Close Date & Time

10 AUG 2020 13:25

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 21:16

PC Open Date & Time

10 AUG 2020 14:20

PC Close Date & Time

11 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 09:41

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:40

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 20:50

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 23:48

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 22:31

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 11:13
PC Open Date & Time	10 AUG 2020 10:55
PC Close Date & Time	10 AUG 2020 13:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 21:17
PC Open Date & Time	10 AUG 2020 14:20
PC Close Date & Time	11 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	12 AUG 2020 09:41
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION (doctor visit,
other)** for any illness or symptoms?

No ☐

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

	Yes ☐
PC Time stamp	
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	13 AUG 2020 12:41
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	14 AUG 2020 20:50
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	15 AUG 2020 23:49
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	16 AUG 2020 22:32
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3412184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	07:50 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 07:50
Temperature (xxx.x)	36.9 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	09:46 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 09:46
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412184

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	08 SEP 2020
What was the treatment time? (00:00-23:59)	09:15 (24 HR)
Treatment Date and Time (derived)	08 SEP 2020 09:15
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3412184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	08 SEP 2020
Collection time (<i>00:00-23:59</i>)	08:31 (24 HR)
Collection date and time (derived)	08 SEP 2020 08:31

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:22:31

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:35	08 SEP 2020 08:35
Nasopharyngeal Swab 2	No		

US3412184

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

Was any **MEDICATION TAKEN today for pain or fever?**

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

08 SEP 2020 09:57

PC Open Date & Time

08 SEP 2020 09:35

PC Close Date & Time

08 SEP 2020 12:05

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °F

Was any **MEDICATION TAKEN today for pain or fever?** Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	08 SEP 2020 20:36
PC Open Date & Time	08 SEP 2020 13:00
PC Close Date & Time	09 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

09 SEP 2020 16:11

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE in °F**

Was any **MEDICATION TAKEN today for pain or fever?** Yes ☐
No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

11 SEP 2020 23:59

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

12 SEP 2020 12:00

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

Was any **MEDICATION TAKEN today for pain or fever?**

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

13 SEP 2020 19:33

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

Was any **MEDICATION TAKEN today for pain or fever**?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

15 SEP 2020 06:33

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 09:57

PC Open Date & Time

08 SEP 2020 09:35

PC Close Date & Time

08 SEP 2020 12:05

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 20:37

PC Open Date & Time

08 SEP 2020 13:00

PC Close Date & Time

09 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 16:12

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 00:00

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:01

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 19:33

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 06:33

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 09:58
PC Open Date & Time	08 SEP 2020 09:35
PC Close Date & Time	08 SEP 2020 12:05

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 20:38
PC Open Date & Time	08 SEP 2020 13:00
PC Close Date & Time	09 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	09 SEP 2020 16:12
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION (doctor visit,
other)** for any illness or symptoms?

No ☐

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

		Yes ☐
PC Time stamp		
PC Open Date & Time		10 SEP 2020 12:00
PC Close Date & Time		11 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	12 SEP 2020 00:00
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	12 SEP 2020 12:02
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	13 SEP 2020 19:34
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	15 SEP 2020 06:35
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3412184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	06 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3412184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	06 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:43 (24 HR)
Collection date and time (derived)	06 OCT 2020 10:43

US3412184

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	10 OCT 2020 06:38:00
Patient Cloud Open Date & Time	10 OCT 2020 00:01
v6.020 DTW (1102)	113 of 1622

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

14 OCT 2020 23:59

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 71

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

21 OCT 2020 22:36:35

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 OCT 2020 12:14:21
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 NOV 2020 07:58:43
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 08:16:55
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 166

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 173

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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17 FEB 2021 00:01

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21 FEB 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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24 FEB 2021 00:01

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28 FEB 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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03 MAR 2021 00:01

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07 MAR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 215

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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14 MAR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 229

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 236

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 278

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 313

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 334

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 376

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 439

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 446

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 516

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 544

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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06 FEB 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

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13 FEB 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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16 FEB 2022 00:01

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20 FEB 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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27 FEB 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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02 MAR 2022 00:01

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US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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30 MAR 2022 00:01

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03 APR 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

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10 APR 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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13 APR 2022 00:01

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17 APR 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

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01 MAY 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 635

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 649

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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12 JUN 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

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19 JUN 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 684

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

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26 JUN 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 691

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

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03 JUL 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

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10 JUL 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

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17 JUL 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

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24 JUL 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

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31 JUL 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
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Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3412184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412184

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412184

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:22:31

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled☐ Clinical Visit - Unscheduled☐ Safety Call☐ Convalescent Tele-visit☐
Has the subject reported symptoms of SARS-COV-2?	Yes☐ No☐

US3412184

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:22:31

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3412184

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:22:31

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

AEID	USA-US061-2020-MRNA-1273-P30 1000002
Adverse event	RIGHT BREAST DUCTAL CARCINOMA IN SITU
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	12 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

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US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

SUBJECT CONTACTED FOR
TELEPHONE VISIT @ 17:30. SHE
NOTES SHE HAD A
MAMMOGRAM AND BIOPSY
LAST WEEK OF HER RIGHT
BREAST ON 12-AUG-2020. SHE
WAS INFORMED THAT THEY
FOUND STAGE 0 BREAST
CANCER (NO INVOLVEMENT
OF LYMPH NODES).
BONE MINERAL DENSITY SCAN
IS IN THE NORMAL RANGE
MRI BREAST BILATERAL W WO
BREAS-ICD-10-CM. D05.11-
INTRADUCTAL CARCINOMA IN
SITU OF RIGHT
BREAST-ICD-10-CM
THE CLIP PLACED AT TIME OF
BIOPSY IS PRESENT IN THE
POSTERIOR
RETROAREOLAR/6:00 PART OF
THE RIGHT BREAST. WITH THE
PATIENT PRONE, THIS IS 9.5 CM
POSTERIOR TO THE NIPPLE.
THERE IS A MINIMAL
ILL-DEFINES 5MM SIZE AREA
OF ENHANCEMENT AT THE
LEVEL OF THE CLIP. NO
EVIDENCE OF MULTICENTRIC
OR MULTIFOCAL
ABNORMALITY. NO
SUSPICIOUS ENHANCEMENT
PRESENT ELSEWHERE IN
EITHER BREAST. NO EVIDENCE
OF AXILLARY OR INTERNAL
MAMMARY CHAIN
ADENOPATHY. KNOWN BIOPSY

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

PROVEN MALIGNANCY. NO
EVIDENCE OF MULTICENTRIC
OR MULTIFOCAL
ABNORMALITY. MINIMAL
POSTBIOPSY CHANGES ON THE
RIGHT ARE PRESENT

SUBJECT IS TAKING PART IN
ANOTHER PHARMACEUTICAL
TRIAL FOR ARIMIDEX FOR
BREAST CANCER. THIS WAS
APPROVED BY THE MEDICAL
MONITOR THAT SUBJECT CAN
CONTINUE WITH FOLLOW UP
AND SITE WILL DOCUMENT
THE PROTOCOL DEVIATION.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:22:31

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

Name of Medication	ADVIL
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS OF KNEE
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ☒ No ☐
Indication	GENERAL HEALTH
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

Name of Medication	OMEGA 3 (FISH OIL)
Prophylaxis	Yes ☒ No ☐
Indication	GENERAL HEALTH
Dose per administration	1000
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

Name of Medication	VITAMIN D3
Prophylaxis	Yes ☒ No ☐
Indication	GENERAL HEALTH
Dose per administration	1000
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☒ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:22:31

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:22:31

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 AUG 2020	MAM STEROTACTIC LOC BREAST BIOPSY RIGHT	Adverse Event	
16 SEP 2020	DX BONE DENSITY AXIAL SKELETON	Adverse Event	
17 SEP 2020	MRI BREAST BILATERAL W WO CONTRAST W CAD	Adverse Event	

US3412184

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:22:31

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3412184

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:22:31

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

SAEID	USA-US061-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:22:31

SAEID	USA-US061-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	18/AUG/2020 09:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:22:31

SAEID	USA-US061-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/OCT/2020 10:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:22:31

SAEID	USA-US061-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/NOV/2020 15:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3412184 (Prod: New Horizons Clinical Research)

US3412184

Form: Participant Creation

Generated On: 26 Nov 2020 09:22:31

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3412184'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 13:19:45

US3412184

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:35:41

US3412184

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 13:19:46

US3412184

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:35:41

US3412184

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	10 Aug 2020 14:35:41

US3412184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1947'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 13:19:47

US3412184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Age](#)

Audit	User	Time (GMT)
User entered '73'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10
	(b) (4)	

US3412184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	10 Aug 2020 14:36:10

US3412184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '73'	System	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

Sex

Audit	User	Time (GMT)
User entered 'Female (F)'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10
	(b) (4)	

US3412184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10

US3412184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

White

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Sep 2020 16:26:45
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	23 Sep 2020 15:49:54
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10
	(b) (4)	

US3412184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Black](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Sep 2020 16:26:45
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	23 Sep 2020 15:49:54
	(b) (4)	
User entered '1'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10
	(b) (4)	

US3412184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10
	(b) (4)	

US3412184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:36:10

US3412184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:36:10

US3412184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10
	(b) (4)	

US3412184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	10 Aug 2020 14:36:10
	(b) (4)	

US3412184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

Unknown

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10
	(b) (4)	

US3412184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	10 Aug 2020 14:36:10
	(b) (4)	

US3412184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:36:25

US3412184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 13:19:46

US3412184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:36:31

US3412184

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:22:31

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:36:31

US3412184

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:22:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:31:05
	(b) (4)	

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:27
User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 11:45:12
Data point term sent to Coder	System	13 Oct 2020 21:38:55
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'has been updated with location' (Site from DM).	Steven Anderson (b) (4) (b) (4)	13 Oct 2020 21:38:16
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	13 Oct 2020 21:38:06
User entered 'OSTEOARTHRITIS Bi-lateral knees' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	13 Oct 2020 21:38:06
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	26 Sep 2020 16:42:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:33:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 23:33:18
Data point term sent to Coder	System	17 Aug 2020 23:32:12
User entered 'Osteoarthritis'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:31:33

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Steven Anderson (b) (4)	17 Aug 2020 23:31:33
	(b) (4)	

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:31:33
	(b) (4)	

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:31:33
	(b) (4)	

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:31:33
	(b) (4)	

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:31:33
	(b) (4)	

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	17 Aug 2020 23:31:33

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2010'	System	17 Aug 2020 23:31:33

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:31:33

US3412184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:31:33

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 21:40:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	13 Oct 2020 21:40:23
Data point term sent to Coder	System	13 Oct 2020 21:38:55
User entered 'Post-menopausal'	Steven Anderson (b) (4)	13 Oct 2020 21:38:55
	(b) (4)	

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1996'	Steven Anderson (b) (4)	13 Oct 2020 21:38:55
	(b) (4)	

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	13 Oct 2020 21:38:55
	(b) (4)	

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1996'	System	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1996'	System	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 21:38:55

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:33:03
	(b) (4)	

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Aug 2020 23:33:25
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	17 Aug 2020 23:33:25
User closed query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	17 Aug 2020 23:33:25
Query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	17 Aug 2020 23:33:25
User entered '10 Aug 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	17 Aug 2020 23:33:25
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Aug 2020 23:33:03
User opened query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	17 Aug 2020 23:33:03
User entered '17 Aug 2020'	Steven Anderson (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:37'	Steven Anderson (b) (4)	17 Aug 2020 23:33:03
	(b) (4)	

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 09:37'	System	17 Aug 2020 23:33:25
User entered '17 Aug 2020 09:37'	System	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '165.6' cm	Steven Anderson (b) (4)	17 Aug 2020 23:33:03
DataPoint set to visible.	(b) (4) System	10 Aug 2020 14:36:31

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '88.1' kg	Steven Anderson (b) (4)	17 Aug 2020 23:33:03
DataPoint set to visible.	(b) (4) System	10 Aug 2020 14:36:31

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '32.12590'	System	16 Sep 2020 23:49:32
User entered '32.1'	System	17 Aug 2020 23:33:03
DataPoint set to visible.	System	10 Aug 2020 14:36:31

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	17 Aug 2020 23:33:03
DataPoint set to visible.	System	10 Aug 2020 14:36:31

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 23:33:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Steven Anderson (b) (4)	17 Aug 2020 23:33:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 23:33:03
User entered '3nd' (non-conformant).	Steven Anderson (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 19:38:05
Query 'Data is required. Please provide.' answered with 'na' (Site from System).	Steven Anderson (b) (4)	17 Aug 2020 23:33:34
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 23:33:03
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 23:33:03

US3412184

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:33:45

US3412184

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 18:07:29
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 12:53:06
User entered '10 Aug 2020'	Steven Anderson (b) (4)	17 Aug 2020 23:33:45
	(b) (4)	

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:34:17

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:34:17
	(b) (4)	

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 11:45:32
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'this has been recorded in med history' (Site from DM).	Steven Anderson (b) (4)	13 Oct 2020 21:39:44
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 05:32:49
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Steven Anderson (b) (4)	17 Aug 2020 23:34:17

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:34:17

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:34:17

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:34:17

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un UNK 1996'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:34:17

US3412184

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:34:17

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43
	(b) (4)	

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43
	(b) (4)	

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43
	(b) (4)	

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

[Warehouse shipping and fulfillment centers](#) and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43
	(b) (4)	

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43
	(b) (4)	

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43
	(b) (4)	

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

[Specify](#)

Audit	User	Time (GMT)
User entered 'Has health care worker come to house for husband'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43
	(b) (4)	

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:37:43
	(b) (4)	

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '1'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

[Other](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Sep 2020 16:00:36
User entered '0'	(b) (4) Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:37:43

US3412184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

[Specify](#)

Audit	User	Time (GMT)
User entered 'Lives in (b) (6) reason for change:	Melissa Fuson (b) (4)	23 Sep 2020 16:00:36
Data Entry Error	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:37:43
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:36:47

US3412184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:36:47

US3412184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:36:47

US3412184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	10 Aug 2020 14:36:47

US3412184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 14:14:26

US3412184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:13:21
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:13:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 14:14:26
User entered '185180' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 14:14:26

US3412184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	10 Aug 2020 14:14:26

US3412184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	10 Aug 2020 14:37:00
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	10 Aug 2020 14:37:00
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:37:00

US3412184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:37:00

US3412184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	10 Aug 2020 14:37:00

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	17 Aug 2020 23:40:05
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:37'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 09:37'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.3' C	Steven Anderson (b) (4)	17 Aug 2020 23:40:05
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '138'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '86'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:13:18
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	17 Aug 2020 23:40:05
User entered '11:06'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:06'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	Steven Anderson (b) (4)	17 Aug 2020 23:40:05
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140'	Steven Anderson (b) (4)	17 Aug 2020 23:40:05
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 23:40:05

US3412184

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:12
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:12

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	10 Aug 2020 14:48:00
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	10 Aug 2020 14:48:00
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	10 Aug 2020 14:48:00
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 14:48:00

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Steven Anderson (b) (4)	10 Aug 2020 14:48:00
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:35'	Steven Anderson (b) (4)	10 Aug 2020 14:48:00
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 10:35'	System	10 Aug 2020 14:48:00

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	10 Aug 2020 14:48:00
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	10 Aug 2020 14:48:00

US3412184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 14:48:00

US3412184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:28
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:28

US3412184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:00'	Steven Anderson (b) (4)	17 Aug 2020 23:40:28
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 10:00'	System	17 Aug 2020 23:40:28

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:22:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:40:46

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:46

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:46
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:09'	Steven Anderson (b) (4)	17 Aug 2020 23:40:46
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 10:09'	System	17 Aug 2020 23:40:46

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:46

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:46
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:40:46
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:40:46

US3412184

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:40:52
	(b) (4)	

US3412184

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 23:40:52

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:07:18', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '262e2caa-520e-4f39-9f61-9b2da846cc75'	System	10 Aug 2020 15:07:54
User entered 'Yes (Y)'	System	10 Aug 2020 15:07:54

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:07:27', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '262e2caa-520e-4f39-9f61-9b2da846cc75'	System	10 Aug 2020 15:07:54
User entered '97.7'	System	10 Aug 2020 15:07:54

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:07:44', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '262e2caa-520e-4f39-9f61-9b2da846cc75'	System	10 Aug 2020 15:07:54
User entered 'No (N)'	System	10 Aug 2020 15:07:54

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:07:51', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '262e2caa-520e-4f39-9f61-9b2da846cc75'	System	10 Aug 2020 15:07:54
User entered '10 Aug 2020 11:07'	System	10 Aug 2020 15:07:54

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 10:55'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 13:25'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:13:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '96ea2e5b-0241-4038-ba10-2297b8b0f81d'	System	11 Aug 2020 01:14:16
User entered 'Yes (Y)'	System	11 Aug 2020 01:14:16

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:14:03', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '96ea2e5b-0241-4038-ba10-2297b8b0f81d' User entered '98.0'	System	11 Aug 2020 01:14:16
	System	11 Aug 2020 01:14:16

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:14:09', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '96ea2e5b-0241-4038-ba10-2297b8b0f81d'	System	11 Aug 2020 01:14:16
User entered 'No (N)'	System	11 Aug 2020 01:14:16

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:14:14', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '96ea2e5b-0241-4038-ba10-2297b8b0f81d'	System	11 Aug 2020 01:14:16
User entered '10 Aug 2020 21:14'	System	11 Aug 2020 01:14:16

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 14:20'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 2'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:40:20', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '904425ef-4fa3-4bb4-b27f-b4d39a3e5221'	System	12 Aug 2020 13:40:46
User entered 'Yes (Y)'	System	12 Aug 2020 13:40:46

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:40:30', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '904425ef-4fa3-4bb4-b27f-b4d39a3e5221'	System	12 Aug 2020 13:40:46
User entered '98.0'	System	12 Aug 2020 13:40:46

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:40:36', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '904425ef-4fa3-4bb4-b27f-b4d39a3e5221'	System	12 Aug 2020 13:40:46
User entered 'No (N)'	System	12 Aug 2020 13:40:46

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:40:43', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '904425ef-4fa3-4bb4-b27f-b4d39a3e5221'	System	12 Aug 2020 13:40:46
User entered '12 Aug 2020 09:40'	System	12 Aug 2020 13:40:46

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 3'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 4'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:39:58', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '442c87cd-904f-4fc0-8b2c-7d39510dcf3d'	System	13 Aug 2020 16:40:17
User entered 'Yes (Y)'	System	13 Aug 2020 16:40:17

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:05', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '442c87cd-904f-4fc0-8b2c-7d39510dcf3d'	System	13 Aug 2020 16:40:17
User entered '97.4'	System	13 Aug 2020 16:40:17

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:10', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '442c87cd-904f-4fc0-8b2c-7d39510dcf3d'	System	13 Aug 2020 16:40:17
User entered 'No (N)'	System	13 Aug 2020 16:40:17

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:15', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '442c87cd-904f-4fc0-8b2c-7d39510dcf3d'	System	13 Aug 2020 16:40:17
User entered '13 Aug 2020 12:40'	System	13 Aug 2020 16:40:17

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 5'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:49:29', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2a97dbbe-5e1f-4c4f-b239-41a5db5165d9'	System	15 Aug 2020 00:49:58
User entered 'Yes (Y)'	System	15 Aug 2020 00:49:58

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:49:36', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2a97dbbe-5e1f-4c4f-b239-41a5db5165d9'	System	15 Aug 2020 00:49:58
User entered '98.0'	System	15 Aug 2020 00:49:58

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:49:51', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2a97dbbe-5e1f-4c4f-b239-41a5db5165d9'	System	15 Aug 2020 00:49:58
User entered 'No (N)'	System	15 Aug 2020 00:49:58

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:49:55', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2a97dbbe-5e1f-4c4f-b239-41a5db5165d9'	System	15 Aug 2020 00:49:58
User entered '14 Aug 2020 20:49'	System	15 Aug 2020 00:49:58

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 6'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:02', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'eb2fcb6a-b94c-461c-874a-8e2128967a34'	System	16 Aug 2020 03:48:26
User entered 'Yes (Y)'	System	16 Aug 2020 03:48:26

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:09', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'eb2fcb6a-b94c-461c-874a-8e2128967a34'	System	16 Aug 2020 03:48:26
User entered '97.6'	System	16 Aug 2020 03:48:26

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:16', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'eb2fcb6a-b94c-461c-874a-8e2128967a34'	System	16 Aug 2020 03:48:26
User entered 'No (N)'	System	16 Aug 2020 03:48:26

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:20', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'eb2fcb6a-b94c-461c-874a-8e2128967a34'	System	16 Aug 2020 03:48:26
User entered '15 Aug 2020 23:48'	System	16 Aug 2020 03:48:26

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 7'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:30:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '58ffdb31-85f4-40ea-901b-25df75918a76'	System	17 Aug 2020 02:31:02
User entered 'Yes (Y)'	System	17 Aug 2020 02:31:02

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:30:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '58ffdb31-85f4-40ea-901b-25df75918a76'	System	17 Aug 2020 02:31:02
User entered '95.6'	System	17 Aug 2020 02:31:02

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:30:55', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '58ffdb31-85f4-40ea-901b-25df75918a76'	System	17 Aug 2020 02:31:02
User entered 'No (N)'	System	17 Aug 2020 02:31:02

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:30:58', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '58ffdb31-85f4-40ea-901b-25df75918a76'	System	17 Aug 2020 02:31:02
User entered '16 Aug 2020 22:30'	System	17 Aug 2020 02:31:02

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:11:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '520c77e9-f9c8-47d9-a623-16ff5f66db22'	System	10 Aug 2020 15:12:32
User entered 'None (1)'	System	10 Aug 2020 15:12:32

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:12:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '520c77e9-f9c8-47d9-a623-16ff5f66db22'	System	10 Aug 2020 15:12:32
User entered 'No (N)'	System	10 Aug 2020 15:12:32

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:12:06', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '520c77e9-f9c8-47d9-a623-16ff5f66db22'	System	10 Aug 2020 15:12:32
User entered 'No (N)'	System	10 Aug 2020 15:12:32

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:12:24', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '520c77e9-f9c8-47d9-a623-16ff5f66db22'	System	10 Aug 2020 15:12:32
User entered 'None (1)'	System	10 Aug 2020 15:12:32

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:12:27', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '520c77e9-f9c8-47d9-a623-16ff5f66db22'	System	10 Aug 2020 15:12:32
User entered '10 Aug 2020 11:12'	System	10 Aug 2020 15:12:32

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 10:55'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 13:25'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:16:11', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '0e616c63-4dbf-40b7-8e58-33def0a6f542'	System	11 Aug 2020 01:16:52
User entered 'None (1)'	System	11 Aug 2020 01:16:52

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:16:31', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '0e616c63-4dbf-40b7-8e58-33def0a6f542'	System	11 Aug 2020 01:16:52
User entered 'No (N)'	System	11 Aug 2020 01:16:52

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:16:38', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '0e616c63-4dbf-40b7-8e58-33def0a6f542'	System	11 Aug 2020 01:16:52
User entered 'No (N)'	System	11 Aug 2020 01:16:52

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:16:45', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '0e616c63-4dbf-40b7-8e58-33def0a6f542'	System	11 Aug 2020 01:16:52
User entered 'None (1)'	System	11 Aug 2020 01:16:52

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:16:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '0e616c63-4dbf-40b7-8e58-33def0a6f542'	System	11 Aug 2020 01:16:52
User entered '10 Aug 2020 21:16'	System	11 Aug 2020 01:16:52

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 14:20'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 2'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:40:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '57529f0a-074e-489f-8d81-21674f44e74c'	System	12 Aug 2020 13:41:06
User entered 'None (1)'	System	12 Aug 2020 13:41:06

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:40:53', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '57529f0a-074e-489f-8d81-21674f44e74c'	System	12 Aug 2020 13:41:06
User entered 'No (N)'	System	12 Aug 2020 13:41:06

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:40:56', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '57529f0a-074e-489f-8d81-21674f44e74c'	System	12 Aug 2020 13:41:06
User entered 'No (N)'	System	12 Aug 2020 13:41:06

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:01', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '57529f0a-074e-489f-8d81-21674f44e74c'	System	12 Aug 2020 13:41:06
User entered 'None (1)'	System	12 Aug 2020 13:41:06

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:04', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '57529f0a-074e-489f-8d81-21674f44e74c'	System	12 Aug 2020 13:41:06
User entered '12 Aug 2020 09:41'	System	12 Aug 2020 13:41:06

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 3'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 4'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:19', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c6027e8a-db68-4b7f-a606-eba4e7512e67'	System	13 Aug 2020 16:40:34
User entered 'None (1)'	System	13 Aug 2020 16:40:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:22', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c6027e8a-db68-4b7f-a606-eba4e7512e67'	System	13 Aug 2020 16:40:34
User entered 'No (N)'	System	13 Aug 2020 16:40:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:25', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c6027e8a-db68-4b7f-a606-eba4e7512e67'	System	13 Aug 2020 16:40:34
User entered 'No (N)'	System	13 Aug 2020 16:40:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:27', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c6027e8a-db68-4b7f-a606-eba4e7512e67'	System	13 Aug 2020 16:40:34
User entered 'None (1)'	System	13 Aug 2020 16:40:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:30', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c6027e8a-db68-4b7f-a606-eba4e7512e67'	System	13 Aug 2020 16:40:34
User entered '13 Aug 2020 12:40'	System	13 Aug 2020 16:40:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 5'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:02', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '043bf993-41b9-4e96-b532-049b4c993433'	System	15 Aug 2020 00:50:25
User entered 'None (1)'	System	15 Aug 2020 00:50:25

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '043bf993-41b9-4e96-b532-049b4c993433'	System	15 Aug 2020 00:50:25
User entered 'No (N)'	System	15 Aug 2020 00:50:25

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:13', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '043bf993-41b9-4e96-b532-049b4c993433'	System	15 Aug 2020 00:50:25
User entered 'No (N)'	System	15 Aug 2020 00:50:25

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:20', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '043bf993-41b9-4e96-b532-049b4c993433'	System	15 Aug 2020 00:50:25
User entered 'None (1)'	System	15 Aug 2020 00:50:25

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:24', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '043bf993-41b9-4e96-b532-049b4c993433'	System	15 Aug 2020 00:50:25
User entered '14 Aug 2020 20:50'	System	15 Aug 2020 00:50:25

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 6'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:26', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '6d2f3ae2-7f24-4fb7-9062-cad85fd9cc7f'	System	16 Aug 2020 03:48:48
User entered 'None (1)'	System	16 Aug 2020 03:48:48

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:30', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '6d2f3ae2-7f24-4fb7-9062-cad85fd9cc7f'	System	16 Aug 2020 03:48:48
User entered 'No (N)'	System	16 Aug 2020 03:48:48

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:37', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '6d2f3ae2-7f24-4fb7-9062-cad85fd9cc7f'	System	16 Aug 2020 03:48:48
User entered 'No (N)'	System	16 Aug 2020 03:48:48

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:44', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '6d2f3ae2-7f24-4fb7-9062-cad85fd9cc7f'	System	16 Aug 2020 03:48:48
User entered 'None (1)'	System	16 Aug 2020 03:48:48

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:47', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '6d2f3ae2-7f24-4fb7-9062-cad85fd9cc7f'	System	16 Aug 2020 03:48:48
User entered '15 Aug 2020 23:48'	System	16 Aug 2020 03:48:48

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 7'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:04', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f9dad119-f419-413d-af2d-1289f73982c3'	System	17 Aug 2020 02:31:34
User entered 'None (1)'	System	17 Aug 2020 02:31:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:12', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f9dad119-f419-413d-af2d-1289f73982c3'	System	17 Aug 2020 02:31:34
User entered 'No (N)'	System	17 Aug 2020 02:31:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:21', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f9dad119-f419-413d-af2d-1289f73982c3'	System	17 Aug 2020 02:31:34
User entered 'No (N)'	System	17 Aug 2020 02:31:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:28', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f9dad119-f419-413d-af2d-1289f73982c3'	System	17 Aug 2020 02:31:34
User entered 'None (1)'	System	17 Aug 2020 02:31:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:31', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f9dad119-f419-413d-af2d-1289f73982c3'	System	17 Aug 2020 02:31:34
User entered '16 Aug 2020 22:31'	System	17 Aug 2020 02:31:34

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:12:47', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f'	System	10 Aug 2020 15:13:19
User entered 'None (0)'	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:12:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f'	System	10 Aug 2020 15:13:19
User entered 'None (0)'	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:12:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f'	System	10 Aug 2020 15:13:19
User entered 'None (0)'	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:13:04', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f'	System	10 Aug 2020 15:13:19
User entered 'None (0)'	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:13:06', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f'	System	10 Aug 2020 15:13:19
User entered 'None (0)'	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:13:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f'	System	10 Aug 2020 15:13:19
User entered 'None (0)'	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:13:13', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f'	System	10 Aug 2020 15:13:19
User entered 'No (N)'	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T11:13:16', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '34d373b1-68b0-4079-be81-b1f36938ed0f'	System	10 Aug 2020 15:13:19
User entered '10 Aug 2020 11:13'	System	10 Aug 2020 15:13:19

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 10:55'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 13:25'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:16:54', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1'	System	11 Aug 2020 01:17:31
User entered 'None (0)'	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:16:59', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1'	System	11 Aug 2020 01:17:31
User entered 'None (0)'	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:17:07', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1'	System	11 Aug 2020 01:17:31
User entered 'None (0)'	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:17:10', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1'	System	11 Aug 2020 01:17:31
User entered 'None (0)'	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:17:13', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1'	System	11 Aug 2020 01:17:31
User entered 'None (0)'	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:17:16', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1'	System	11 Aug 2020 01:17:31
User entered 'None (0)'	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:17:24', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1'	System	11 Aug 2020 01:17:31
User entered 'No (N)'	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-10T21:17:28', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'c15be117-7434-4bd5-bda2-19c686d753c1'	System	11 Aug 2020 01:17:31
User entered '10 Aug 2020 21:17'	System	11 Aug 2020 01:17:31

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 14:20'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 2'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:11', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf'	System	12 Aug 2020 13:41:34
User entered 'None (0)'	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:14', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf'	System	12 Aug 2020 13:41:34
User entered 'None (0)'	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:17', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf'	System	12 Aug 2020 13:41:34
User entered 'None (0)'	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:20', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf' User entered 'None (0)'	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:23', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf'	System	12 Aug 2020 13:41:34
User entered 'None (0)'	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:25', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf'	System	12 Aug 2020 13:41:34
User entered 'None (0)'	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:29', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf'	System	12 Aug 2020 13:41:34
User entered 'No (N)'	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-12T09:41:32', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b26a818f-55f8-402f-b998-e3efbfc194cf'	System	12 Aug 2020 13:41:34
User entered '12 Aug 2020 09:41'	System	12 Aug 2020 13:41:34

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 3'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 4'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:35', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf'	System	13 Aug 2020 16:41:02
User entered 'None (0)'	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:40', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf'	System	13 Aug 2020 16:41:02
User entered 'None (0)'	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:44', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf'	System	13 Aug 2020 16:41:02
User entered 'None (0)'	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:47', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf'	System	13 Aug 2020 16:41:02
User entered 'None (0)'	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf'	System	13 Aug 2020 16:41:02
User entered 'None (0)'	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf'	System	13 Aug 2020 16:41:02
User entered 'None (0)'	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:40:59', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf'	System	13 Aug 2020 16:41:02
User entered 'No (N)'	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-13T12:41:01', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'e1592033-4fbd-4acc-b587-d4c25a5a0bcf'	System	13 Aug 2020 16:41:02
User entered '13 Aug 2020 12:41'	System	13 Aug 2020 16:41:02

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 5'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:29', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce'	System	15 Aug 2020 00:51:01
User entered 'None (0)'	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:31', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce'	System	15 Aug 2020 00:51:01
User entered 'None (0)'	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:34', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce'	System	15 Aug 2020 00:51:01
User entered 'None (0)'	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:36', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce'	System	15 Aug 2020 00:51:01
User entered 'None (0)'	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:38', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce'	System	15 Aug 2020 00:51:01
User entered 'None (0)'	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce'	System	15 Aug 2020 00:51:01
User entered 'None (0)'	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:56', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce'	System	15 Aug 2020 00:51:01
User entered 'No (N)'	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-14T20:50:59', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'dc1a34cc-e000-4ff6-a91c-6e8e7c354fce'	System	15 Aug 2020 00:51:01
User entered '14 Aug 2020 20:50'	System	15 Aug 2020 00:51:01

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 6'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0'	System	16 Aug 2020 03:49:32
User entered 'None (0)'	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:55', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0'	System	16 Aug 2020 03:49:32
User entered 'None (0)'	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:48:58', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0'	System	16 Aug 2020 03:49:32
User entered 'None (0)'	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:49:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0'	System	16 Aug 2020 03:49:32
User entered 'None (0)'	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:49:03', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0'	System	16 Aug 2020 03:49:32
User entered 'None (0)'	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:49:06', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0'	System	16 Aug 2020 03:49:32
User entered 'None (0)'	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:49:12', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0'	System	16 Aug 2020 03:49:32
User entered 'No (N)'	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-15T23:49:27', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '015ec42f-0d96-44fb-8cf9-b8a5ce033ac0'	System	16 Aug 2020 03:49:32
User entered '15 Aug 2020 23:49'	System	16 Aug 2020 03:49:32

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 7'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:36', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb'	System	17 Aug 2020 02:32:25
User entered 'None (0)'	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:42', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb' User entered 'None (0)'	System	17 Aug 2020 02:32:25
	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:45', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb'	System	17 Aug 2020 02:32:25
User entered 'None (0)'	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:48', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb' User entered 'None (0)'	System	17 Aug 2020 02:32:25
	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:51', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb'	System	17 Aug 2020 02:32:25
User entered 'None (0)'	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:31:54', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb'	System	17 Aug 2020 02:32:25
User entered 'None (0)'	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:32:19', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb'	System	17 Aug 2020 02:32:25
User entered 'No (N)'	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-08-16T22:32:22', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd9fecebd-fb06-4599-82e8-1b10bae0a6fb'	System	17 Aug 2020 02:32:25
User entered '16 Aug 2020 22:32'	System	17 Aug 2020 02:32:25

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 14:48:00

US3412184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:41:15
	(b) (4)	

US3412184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:41:15

US3412184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	17 Aug 2020 23:41:15

US3412184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:41:15

US3412184

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:42:15
	(b) (4)	

US3412184

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 23:42:15

US3412184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	24 Aug 2020 21:31:36
	(b) (4)	

US3412184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Steven Anderson (b) (4) (b) (4)	24 Aug 2020 21:31:36

US3412184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	24 Aug 2020 21:31:36
	(b) (4)	

US3412184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	24 Aug 2020 21:31:36

US3412184

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	24 Aug 2020 21:31:41
	(b) (4)	

US3412184

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 21:31:41

US3412184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 12:45:28

US3412184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 12:45:28

US3412184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Sep 2020 12:45:28

US3412184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 12:45:28

US3412184

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 12:45:32

US3412184

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 12:45:32

US3412184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	08 Sep 2020 12:53:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Steven Anderson (b) (4)	08 Sep 2020 12:53:06
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	08 Sep 2020 12:53:06
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	08 Sep 2020 12:53:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Steven Anderson (b) (4) (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '07:50'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 07:50'	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.9' C	Steven Anderson (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Steven Anderson (b) (4) (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '78'	Steven Anderson (b) (4) (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '78'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 13:56:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 13:56:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:56:47
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 12:53:57
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:56:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:46' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:56:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 09:46'	System	08 Sep 2020 13:56:47
User entered empty.	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.5' F reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:56:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:56:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	08 Sep 2020 12:53:57
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:56:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 13:56:47
User entered empty.	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:56:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 13:56:47
User entered empty.	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:56:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 13:56:47
User entered empty.	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '80' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:56:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 13:56:47
User entered empty.	System	08 Sep 2020 12:53:57

US3412184

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Sep 2020 12:54:10
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Steven Anderson (b) (4) (b) (4)	08 Sep 2020 12:54:10

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:15'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 09:15'	System	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 13:55:06

US3412184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Sep 2020 12:54:33
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Steven Anderson (b) (4)	08 Sep 2020 12:54:33
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '08:31'	Steven Anderson (b) (4)	08 Sep 2020 12:54:33
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 08:31'	System	08 Sep 2020 12:54:33

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:22:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Steven Anderson (b) (4) (b) (4)	08 Sep 2020 12:54:54

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Steven Anderson (b) (4)	08 Sep 2020 12:54:54

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Sep 2020 12:54:54
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '08:35'	Steven Anderson (b) (4)	08 Sep 2020 12:54:54
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 08:35'	System	08 Sep 2020 12:54:54

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Steven Anderson (b) (4)	08 Sep 2020 12:54:54

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	08 Sep 2020 12:54:54
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	08 Sep 2020 12:54:54
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 12:54:54

US3412184

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Sep 2020 12:55:00
	(b) (4)	

US3412184

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 12:55:00

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:56:37', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '12e26ba2-a110-4d78-af6a-0b261d56fe9c'	System	08 Sep 2020 13:57:09
User entered 'Yes (Y)'	System	08 Sep 2020 13:57:09

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:56:46', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '12e26ba2-a110-4d78-af6a-0b261d56fe9c'	System	08 Sep 2020 13:57:09
User entered '97.5'	System	08 Sep 2020 13:57:09

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:56:59', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '12e26ba2-a110-4d78-af6a-0b261d56fe9c'	System	08 Sep 2020 13:57:09
User entered 'No (N)'	System	08 Sep 2020 13:57:09

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:04', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '12e26ba2-a110-4d78-af6a-0b261d56fe9c'	System	08 Sep 2020 13:57:09
User entered '08 Sep 2020 09:57'	System	08 Sep 2020 13:57:09

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 09:35'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:05'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:36:29', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '03d8e9f9-1d7e-40a5-ba6e-2e110a280b36'	System	09 Sep 2020 00:36:48
User entered 'Yes (Y)'	System	09 Sep 2020 00:36:48

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:36:37', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '03d8e9f9-1d7e-40a5-ba6e-2e110a280b36'	System	09 Sep 2020 00:36:48
User entered '97.3'	System	09 Sep 2020 00:36:48

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:36:42', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '03d8e9f9-1d7e-40a5-ba6e-2e110a280b36'	System	09 Sep 2020 00:36:48
User entered 'No (N)'	System	09 Sep 2020 00:36:48

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:36:46', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '03d8e9f9-1d7e-40a5-ba6e-2e110a280b36'	System	09 Sep 2020 00:36:48
User entered '08 Sep 2020 20:36'	System	09 Sep 2020 00:36:48

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 13:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 2'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:11:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '99129417-8489-42cc-b354-a2010fd01309'	System	09 Sep 2020 20:11:46
User entered 'Yes (Y)'	System	09 Sep 2020 20:11:46

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:11:33', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '99129417-8489-42cc-b354-a2010fd01309'	System	09 Sep 2020 20:11:46
User entered '98.0'	System	09 Sep 2020 20:11:46

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:11:37', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '99129417-8489-42cc-b354-a2010fd01309'	System	09 Sep 2020 20:11:46
User entered 'No (N)'	System	09 Sep 2020 20:11:46

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:11:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '99129417-8489-42cc-b354-a2010fd01309'	System	09 Sep 2020 20:11:46
User entered '09 Sep 2020 16:11'	System	09 Sep 2020 20:11:46

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 3'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 4'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-11T23:59:29', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '68ea595f-04f0-4fdc-9b83-8501ad901dc2'	System	12 Sep 2020 03:59:50
User entered 'Yes (Y)'	System	12 Sep 2020 03:59:50

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-11T23:59:37', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '68ea595f-04f0-4fdc-9b83-8501ad901dc2'	System	12 Sep 2020 03:59:50
User entered '97.3'	System	12 Sep 2020 03:59:50

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-11T23:59:44', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '68ea595f-04f0-4fdc-9b83-8501ad901dc2'	System	12 Sep 2020 03:59:50
User entered 'No (N)'	System	12 Sep 2020 03:59:50

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-11T23:59:48', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '68ea595f-04f0-4fdc-9b83-8501ad901dc2'	System	12 Sep 2020 03:59:50
User entered '11 Sep 2020 23:59'	System	12 Sep 2020 03:59:50

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 5'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:00:23', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2b554587-0c09-4ab9-b429-3826c4ca77a9'	System	12 Sep 2020 16:02:19
User entered 'Yes (Y)'	System	12 Sep 2020 16:02:19

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:00:30', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2b554587-0c09-4ab9-b429-3826c4ca77a9'	System	12 Sep 2020 16:02:19
User entered '97.4'	System	12 Sep 2020 16:02:19

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:00:36', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2b554587-0c09-4ab9-b429-3826c4ca77a9'	System	12 Sep 2020 16:02:19
User entered 'No (N)'	System	12 Sep 2020 16:02:19

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:00:43', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '2b554587-0c09-4ab9-b429-3826c4ca77a9'	System	12 Sep 2020 16:02:19
User entered '12 Sep 2020 12:00'	System	12 Sep 2020 16:02:19

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 6'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:17', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'addb8dfd-d5be-45f3-9603-60b85895d39d' User entered 'Yes (Y)'	System	13 Sep 2020 23:33:36
	System	13 Sep 2020 23:33:36

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:23', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'addb8dfd-d5be-45f3-9603-60b85895d39d' User entered '97.3'	System	13 Sep 2020 23:33:36
	System	13 Sep 2020 23:33:36

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:26', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'addb8dfd-d5be-45f3-9603-60b85895d39d'	System	13 Sep 2020 23:33:36
User entered 'No (N)'	System	13 Sep 2020 23:33:36

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:31', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'addb8dfd-d5be-45f3-9603-60b85895d39d' User entered '13 Sep 2020 19:33'	System	13 Sep 2020 23:33:36
	System	13 Sep 2020 23:33:36

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 7'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:11', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '8a246b6e-a15e-48e2-9017-2a009d628a49'	System	15 Sep 2020 10:33:33
User entered 'Yes (Y)'	System	15 Sep 2020 10:33:33

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:20', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '8a246b6e-a15e-48e2-9017-2a009d628a49'	System	15 Sep 2020 10:33:33
User entered '97.6'	System	15 Sep 2020 10:33:33

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:27', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '8a246b6e-a15e-48e2-9017-2a009d628a49'	System	15 Sep 2020 10:33:33
User entered 'No (N)'	System	15 Sep 2020 10:33:33

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:31', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '8a246b6e-a15e-48e2-9017-2a009d628a49'	System	15 Sep 2020 10:33:33
User entered '15 Sep 2020 06:33'	System	15 Sep 2020 10:33:33

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:19', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b481ceb9-e184-4aa1-8b15-b2fba7b082bc'	System	08 Sep 2020 13:57:43
User entered 'None (1)'	System	08 Sep 2020 13:57:43

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:27', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b481ceb9-e184-4aa1-8b15-b2fba7b082bc'	System	08 Sep 2020 13:57:43
User entered 'No (N)'	System	08 Sep 2020 13:57:43

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:31', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b481ceb9-e184-4aa1-8b15-b2fba7b082bc'	System	08 Sep 2020 13:57:43
User entered 'No (N)'	System	08 Sep 2020 13:57:43

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:38', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b481ceb9-e184-4aa1-8b15-b2fba7b082bc'	System	08 Sep 2020 13:57:43
User entered 'None (1)'	System	08 Sep 2020 13:57:43

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b481ceb9-e184-4aa1-8b15-b2fba7b082bc'	System	08 Sep 2020 13:57:43
User entered '08 Sep 2020 09:57'	System	08 Sep 2020 13:57:43

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 09:35'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:05'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:36:51', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '24ea786f-41a7-4e3d-a0ef-7bb5eae36bc1'	System	09 Sep 2020 00:37:12
User entered 'None (1)'	System	09 Sep 2020 00:37:12

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:36:57', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '24ea786f-41a7-4e3d-a0ef-7bb5eae36bc1'	System	09 Sep 2020 00:37:12
User entered 'No (N)'	System	09 Sep 2020 00:37:12

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '24ea786f-41a7-4e3d-a0ef-7bb5eae36bc1'	System	09 Sep 2020 00:37:12
User entered 'No (N)'	System	09 Sep 2020 00:37:12

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:04', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '24ea786f-41a7-4e3d-a0ef-7bb5eae36bc1'	System	09 Sep 2020 00:37:12
User entered 'None (1)'	System	09 Sep 2020 00:37:12

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:07', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '24ea786f-41a7-4e3d-a0ef-7bb5eae36bc1'	System	09 Sep 2020 00:37:12
User entered '08 Sep 2020 20:37'	System	09 Sep 2020 00:37:12

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 13:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 2'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:11:55', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'a1255f74-faad-4797-843c-36b91da769eb'	System	09 Sep 2020 20:12:16
User entered 'None (1)'	System	09 Sep 2020 20:12:16

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:11:59', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'a1255f74-faad-4797-843c-36b91da769eb'	System	09 Sep 2020 20:12:16
User entered 'No (N)'	System	09 Sep 2020 20:12:16

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:03', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'a1255f74-faad-4797-843c-36b91da769eb'	System	09 Sep 2020 20:12:16
User entered 'No (N)'	System	09 Sep 2020 20:12:16

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:10', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'a1255f74-faad-4797-843c-36b91da769eb'	System	09 Sep 2020 20:12:16
User entered 'None (1)'	System	09 Sep 2020 20:12:16

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:13', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'a1255f74-faad-4797-843c-36b91da769eb'	System	09 Sep 2020 20:12:16
User entered '09 Sep 2020 16:12'	System	09 Sep 2020 20:12:16

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 3'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 4'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-11T23:59:53', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '26e3094b-72eb-4a30-950f-7e5c05523536'	System	12 Sep 2020 04:00:11
User entered 'None (1)'	System	12 Sep 2020 04:00:11

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-11T23:59:58', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '26e3094b-72eb-4a30-950f-7e5c05523536'	System	12 Sep 2020 04:00:11
User entered 'No (N)'	System	12 Sep 2020 04:00:11

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:02', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '26e3094b-72eb-4a30-950f-7e5c05523536'	System	12 Sep 2020 04:00:11
User entered 'No (N)'	System	12 Sep 2020 04:00:11

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:06', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '26e3094b-72eb-4a30-950f-7e5c05523536'	System	12 Sep 2020 04:00:11
User entered 'None (1)'	System	12 Sep 2020 04:00:11

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:09', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '26e3094b-72eb-4a30-950f-7e5c05523536'	System	12 Sep 2020 04:00:11
User entered '12 Sep 2020 00:00'	System	12 Sep 2020 04:00:11

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 5'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:00:53', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '08742a21-6826-4a66-9cf6-e1326ceec6bc'	System	12 Sep 2020 16:04:19
User entered 'None (1)'	System	12 Sep 2020 16:04:19

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:00:58', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '08742a21-6826-4a66-9cf6-e1326ceec6bc'	System	12 Sep 2020 16:04:19
User entered 'No (N)'	System	12 Sep 2020 16:04:19

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:01:03', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '08742a21-6826-4a66-9cf6-e1326ceec6bc'	System	12 Sep 2020 16:04:19
User entered 'No (N)'	System	12 Sep 2020 16:04:19

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:01:07', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '08742a21-6826-4a66-9cf6-e1326ceec6bc'	System	12 Sep 2020 16:04:19
User entered 'None (1)'	System	12 Sep 2020 16:04:19

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:01:16', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '08742a21-6826-4a66-9cf6-e1326ceec6bc'	System	12 Sep 2020 16:04:19
User entered '12 Sep 2020 12:01'	System	12 Sep 2020 16:04:19

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 6'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:37', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '80aa49e2-9747-4822-b70b-4b1e54a3a6be'	System	13 Sep 2020 23:33:55
User entered 'None (1)'	System	13 Sep 2020 23:33:55

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '80aa49e2-9747-4822-b70b-4b1e54a3a6be'	System	13 Sep 2020 23:33:55
User entered 'No (N)'	System	13 Sep 2020 23:33:55

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:46', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '80aa49e2-9747-4822-b70b-4b1e54a3a6be' User entered 'No (N)'	System	13 Sep 2020 23:33:55
	System	13 Sep 2020 23:33:55

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:51', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '80aa49e2-9747-4822-b70b-4b1e54a3a6be'	System	13 Sep 2020 23:33:55
User entered 'None (1)'	System	13 Sep 2020 23:33:55

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:33:53', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '80aa49e2-9747-4822-b70b-4b1e54a3a6be' User entered '13 Sep 2020 19:33'	System	13 Sep 2020 23:33:55
	System	13 Sep 2020 23:33:55

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 7'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:35', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'be4849fe-dd61-46e4-8dce-facb280599f6'	System	15 Sep 2020 10:34:01
User entered 'None (1)'	System	15 Sep 2020 10:34:01

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'be4849fe-dd61-46e4-8dce-facb280599f6'	System	15 Sep 2020 10:34:01
User entered 'No (N)'	System	15 Sep 2020 10:34:01

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'be4849fe-dd61-46e4-8dce-facb280599f6'	System	15 Sep 2020 10:34:01
User entered 'No (N)'	System	15 Sep 2020 10:34:01

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:54', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'be4849fe-dd61-46e4-8dce-facb280599f6'	System	15 Sep 2020 10:34:01
User entered 'None (1)'	System	15 Sep 2020 10:34:01

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:33:57', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'be4849fe-dd61-46e4-8dce-facb280599f6' User entered '15 Sep 2020 06:33'	System	15 Sep 2020 10:34:01
	System	15 Sep 2020 10:34:01

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:46', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d'	System	08 Sep 2020 13:58:09
User entered 'None (0)'	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d'	System	08 Sep 2020 13:58:09
User entered 'None (0)'	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d'	System	08 Sep 2020 13:58:09
User entered 'None (0)'	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:55', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d'	System	08 Sep 2020 13:58:09
User entered 'None (0)'	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:57:58', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d'	System	08 Sep 2020 13:58:09
User entered 'None (0)'	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:58:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d'	System	08 Sep 2020 13:58:09
User entered 'None (0)'	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:58:04', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d'	System	08 Sep 2020 13:58:09
User entered 'No (N)'	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T09:58:07', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'f97735ed-83ad-4ffd-aa20-8161026f676d'	System	08 Sep 2020 13:58:09
User entered '08 Sep 2020 09:58'	System	08 Sep 2020 13:58:09

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 09:35'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:05'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:35', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68'	System	09 Sep 2020 00:38:16
User entered 'None (0)'	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:38', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68'	System	09 Sep 2020 00:38:16
User entered 'None (0)'	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68'	System	09 Sep 2020 00:38:16
User entered 'None (0)'	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:44', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68'	System	09 Sep 2020 00:38:16
User entered 'None (0)'	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:47', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68'	System	09 Sep 2020 00:38:16
User entered 'None (0)'	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68'	System	09 Sep 2020 00:38:16
User entered 'None (0)'	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:37:53', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68'	System	09 Sep 2020 00:38:16
User entered 'No (N)'	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-08T20:38:11', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '364af106-36e4-4850-9fac-9afdae440e68'	System	09 Sep 2020 00:38:16
User entered '08 Sep 2020 20:38'	System	09 Sep 2020 00:38:16

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 13:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 2'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:18', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b'	System	09 Sep 2020 20:12:47
User entered 'None (0)'	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:20', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b'	System	09 Sep 2020 20:12:47
User entered 'None (0)'	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:23', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b'	System	09 Sep 2020 20:12:47
User entered 'None (0)'	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:26', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b'	System	09 Sep 2020 20:12:47
User entered 'None (0)'	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:29', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b'	System	09 Sep 2020 20:12:47
User entered 'None (0)'	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:33', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b'	System	09 Sep 2020 20:12:47
User entered 'None (0)'	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:37', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b'	System	09 Sep 2020 20:12:47
User entered 'No (N)'	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-09T16:12:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '31694c1c-1ebf-4b4f-9a1e-aa6468a7c74b'	System	09 Sep 2020 20:12:47
User entered '09 Sep 2020 16:12'	System	09 Sep 2020 20:12:47

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 3'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 4'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:16', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30'	System	12 Sep 2020 04:00:46
User entered 'None (0)'	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:19', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30'	System	12 Sep 2020 04:00:46
User entered 'None (0)'	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:23', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30'	System	12 Sep 2020 04:00:46
User entered 'None (0)'	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:26', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30'	System	12 Sep 2020 04:00:46
User entered 'None (0)'	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:29', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30'	System	12 Sep 2020 04:00:46
User entered 'None (0)'	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:33', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30'	System	12 Sep 2020 04:00:46
User entered 'None (0)'	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:40', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30'	System	12 Sep 2020 04:00:46
User entered 'No (N)'	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T00:00:43', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '1a0569ca-3dc0-4792-a35a-02357a5f6c30'	System	12 Sep 2020 04:00:46
User entered '12 Sep 2020 00:00'	System	12 Sep 2020 04:00:46

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 5'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:01:35', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156'	System	12 Sep 2020 16:07:20
User entered 'None (0)'	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:01:39', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156'	System	12 Sep 2020 16:07:20
User entered 'None (0)'	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:01:53', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156'	System	12 Sep 2020 16:07:20
User entered 'None (0)'	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:02:02', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156'	System	12 Sep 2020 16:07:20
User entered 'None (0)'	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:02:05', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156'	System	12 Sep 2020 16:07:20
User entered 'None (0)'	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:02:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156'	System	12 Sep 2020 16:07:20
User entered 'None (0)'	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:02:13', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156'	System	12 Sep 2020 16:07:20
User entered 'No (N)'	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-12T12:02:16', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9ca47502-b5be-4d96-af14-eb0cd68e0156'	System	12 Sep 2020 16:07:20
User entered '12 Sep 2020 12:02'	System	12 Sep 2020 16:07:20

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 6'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987'	System	13 Sep 2020 23:34:43
User entered 'None (0)'	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:17', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987'	System	13 Sep 2020 23:34:43
User entered 'None (0)'	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:23', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987'	System	13 Sep 2020 23:34:43
User entered 'None (0)'	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:26', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987'	System	13 Sep 2020 23:34:43
User entered 'None (0)'	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:31', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987'	System	13 Sep 2020 23:34:43
User entered 'None (0)'	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:34', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987'	System	13 Sep 2020 23:34:43
User entered 'None (0)'	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:38', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987'	System	13 Sep 2020 23:34:43
User entered 'No (N)'	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-13T19:34:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'b3e66049-02c5-46b5-b545-5dbafe4ec987'	System	13 Sep 2020 23:34:43
User entered '13 Sep 2020 19:34'	System	13 Sep 2020 23:34:43

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 13:55:06
User entered 'Day 7'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:34:09', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512'	System	15 Sep 2020 10:35:13
User entered 'None (0)'	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:34:32', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512'	System	15 Sep 2020 10:35:13
User entered 'None (0)'	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:34:40', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512'	System	15 Sep 2020 10:35:13
User entered 'None (0)'	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:34:43', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512'	System	15 Sep 2020 10:35:13
User entered 'None (0)'	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:34:46', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512'	System	15 Sep 2020 10:35:13
User entered 'None (0)'	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:34:49', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512'	System	15 Sep 2020 10:35:13
User entered 'None (0)'	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:35:01', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512'	System	15 Sep 2020 10:35:13
User entered 'No (N)'	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-09-15T06:35:11', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'beb3d972-56cc-4cdd-8c02-60bc23c0e512'	System	15 Sep 2020 10:35:13
User entered '15 Sep 2020 06:35'	System	15 Sep 2020 10:35:13

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 13:55:06

US3412184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 13:55:06

US3412184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	23 Sep 2020 16:34:22

US3412184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Melissa Fuson (b) (4) (b) (4)	23 Sep 2020 16:34:22

US3412184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Melissa Fuson (b) (4) (b) (4)	23 Sep 2020 16:34:22

US3412184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Sep 2020 16:34:22

US3412184

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 20:30:27

US3412184

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 20:30:27

US3412184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	22 Sep 2020 18:55:10

US3412184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Mason Urban (b) (4) (b) (4)	22 Sep 2020 18:55:10

US3412184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	22 Sep 2020 18:55:10

US3412184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mason Urban (b) (4) (b) (4)	22 Sep 2020 18:55:10

US3412184

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	22 Sep 2020 18:55:25

US3412184

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 18:55:25

US3412184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	29 Sep 2020 18:55:34

US3412184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Mason Urban (b) (4) (b) (4)	29 Sep 2020 18:55:34

US3412184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	29 Sep 2020 18:55:34

US3412184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mason Urban (b) (4) (b) (4)	29 Sep 2020 18:55:34

US3412184

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	29 Sep 2020 18:55:38

US3412184

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 18:55:38

US3412184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 16:31:07
	(b) (4)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020'	Steven Anderson (b) (4)	06 Oct 2020 16:31:07
	(b) (4)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	06 Oct 2020 16:31:07

US3412184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	06 Oct 2020 16:31:07

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	06 Oct 2020 16:31:18
	(b) (4)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18
	(b) (4)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18
	(b) (4)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18
	(b) (4)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18
	(b) (4)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18
	(b) (4)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18
	(b) (4)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18
	(b) (4)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 16:31:18
	(b) (4)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 16:31:18

US3412184

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	24 Nov 2020 16:18:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 16:31:33

US3412184

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	24 Nov 2020 16:18:30
User entered '06 Oct 2020'	Steven Anderson (b) (4)	06 Oct 2020 16:31:33

US3412184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 16:31:50
	(b) (4)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Oct 2020'	Steven Anderson (b) (4)	06 Oct 2020 16:31:50
	(b) (4)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:43'	Steven Anderson (b) (4)	06 Oct 2020 16:31:50
	(b) (4)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 10:43'	System	06 Oct 2020 16:31:50

US3412184

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 16:31:57
	(b) (4)	

US3412184

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:31:57

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 64'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:36:18', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered 'Yes (Y)'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:36:26', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d'	System	10 Oct 2020 10:38:11
User entered 'No (N)'	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:36:39', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered 'Yes (Y)'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '1'	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '1'	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '1'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d'	System	10 Oct 2020 10:38:11
User entered '1'	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d'	System	10 Oct 2020 10:38:11
User entered '1'	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:08', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '0'	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:24', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d'	System	10 Oct 2020 10:38:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:38', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d'	System	10 Oct 2020 10:38:11
User entered 'Yes (Y)'	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:37:50', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d'	System	10 Oct 2020 10:38:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-10T06:38:00', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '849b2e3c-e3ba-48db-96ea-7a1059d8c69d' User entered '10 Oct 2020 06:38:00'	System	10 Oct 2020 10:38:11
	System	10 Oct 2020 10:38:11

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 71'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-21T22:36:23', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd5475de7-1003-4c32-bcca-69f9088ba718'	System	22 Oct 2020 02:36:39
User entered 'No (N)'	System	22 Oct 2020 02:36:39

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-21T22:36:32', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd5475de7-1003-4c32-bcca-69f9088ba718'	System	22 Oct 2020 02:36:39
User entered 'No (N)'	System	22 Oct 2020 02:36:39

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-21T22:36:35', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: 'd5475de7-1003-4c32-bcca-69f9088ba718' User entered '21 Oct 2020 22:36:35'	System	22 Oct 2020 02:36:39
	System	22 Oct 2020 02:36:39

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 78'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-26T12:14:11', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '3d134859-9fb2-483a-9908-32135da4bfa0' User entered 'No (N)'	System	26 Oct 2020 16:14:24
	System	26 Oct 2020 16:14:24

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-26T12:14:16', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '3d134859-9fb2-483a-9908-32135da4bfa0'	System	26 Oct 2020 16:14:24
User entered 'No (N)'	System	26 Oct 2020 16:14:24

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-10-26T12:14:21', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '3d134859-9fb2-483a-9908-32135da4bfa0' User entered '26 Oct 2020 12:14:21'	System	26 Oct 2020 16:14:24
	System	26 Oct 2020 16:14:24

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 92'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-11-07T07:58:25', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9fa1d38d-851b-4a73-8462-c11d251eb0b6'	System	07 Nov 2020 12:58:47
User entered 'No (N)'	System	07 Nov 2020 12:58:47

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-11-07T07:58:33', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9fa1d38d-851b-4a73-8462-c11d251eb0b6'	System	07 Nov 2020 12:58:47
User entered 'No (N)'	System	07 Nov 2020 12:58:47

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-11-07T07:58:43', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '9fa1d38d-851b-4a73-8462-c11d251eb0b6'	System	07 Nov 2020 12:58:47
User entered '07 Nov 2020 07:58:43'	System	07 Nov 2020 12:58:47

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered 'Day 99'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-11-14T08:15:26', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '66ceb045-b310-49c9-97be-1960b88504f7'	System	14 Nov 2020 13:17:07
User entered 'No (N)'	System	14 Nov 2020 13:17:07

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-11-14T08:16:41', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '66ceb045-b310-49c9-97be-1960b88504f7'	System	14 Nov 2020 13:17:07
User entered 'Yes (Y)'	System	14 Nov 2020 13:17:07

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-11-14T08:16:52', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '66ceb045-b310-49c9-97be-1960b88504f7'	System	14 Nov 2020 13:17:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Nov 2020 13:17:07

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (63C78D1B-A891-413A-BA58-C2E172B44955)', Time: '2020-11-14T08:16:55', User OID: 'PatientReportedOutcome (US3412184)', ODM File OID: '66ceb045-b310-49c9-97be-1960b88504f7'	System	14 Nov 2020 13:17:07
User entered '14 Nov 2020 08:16:55'	System	14 Nov 2020 13:17:07

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 14:48:00

US3412184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Aug 2020 14:48:00
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 14:48:00

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '07 Oct 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '11 Oct 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '14 Oct 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '18 Oct 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '21 Oct 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '25 Oct 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '28 Oct 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '01 Nov 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '04 Nov 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '08 Nov 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '11 Nov 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '15 Nov 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 16:57:13

US3412184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:57:13
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 16:57:13

US3412184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	03 Nov 2020 21:09:52

US3412184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '3 Nov 2020'	Mason Urban (b) (4) (b) (4)	03 Nov 2020 21:09:52

US3412184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	03 Nov 2020 21:09:52

US3412184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mason Urban (b) (4) (b) (4)	03 Nov 2020 21:09:52

US3412184

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	03 Nov 2020 21:10:07

US3412184

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 21:10:07

US3412184

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:22:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:39
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:42:22

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:56
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:03
User entered 'USA-US061-2020-mRNA-1273-P301000002'	System	18 Aug 2020 13:40:20
User entered 'New'	(b) (4), (b) (6)	18 Aug 2020 13:40:20

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider updating the event term to right breast ductal carcinoma in situ.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:33:04
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Intraductal proliferative breast lesion, LLT: Carcinoma in situ of breast ductal - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 00:35:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 00:35:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:01:25
Data point term sent to Coder	System	10 Nov 2020 20:39:20
Query 'PV Query: Please consider updating the event term to right breast ductal carcinoma in situ.' answered with 'Term has been updated' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:38:31
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:38:21
User entered 'right breast ductal carcinoma in situ' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 20:38:21
User opened query 'PV Query: Please consider updating the event term to right breast ductal carcinoma in situ.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:59:09
User closed query 'Per MM, please review and confirm if the subject meets the criteria for discontinuation of study treatment, as per protocol 7.2' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:49:36
Query 'Per MM, please review and confirm if the subject meets the criteria for discontinuation of study treatment, as per protocol 7.2' answered with 'This SAE was submitted to e-pip and per MM and sponsor subject was eligible to continue in the study. All documentation is filed in subject chart.' (Site from DM).	Steven Anderson (b) (4) (b) (4)	20 Oct 2020 21:38:24
User opened query 'Per MM, please review and confirm if the subject meets the criteria for discontinuation of study treatment, as per protocol 7.2' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:16:43

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:56:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:56:17
Data point term sent to Coder	System	17 Aug 2020 23:46:33
User entered 'Breast Cancer Stage 0'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:58
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:00
User entered 'No (N)'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:01
Query 'Per CDM, a response Yes/No is required for this field. Please update accordingly' canceled (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 14:54:17
User entered 'No (N)'	Steven Anderson (b) (4)	10 Sep 2020 16:32:36
User opened query 'Per CDM, a response Yes/No is required for this field. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:40:21
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:13:19

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:06
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 17:25:46
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	08 Sep 2020 13:55:06
User entered '12 Aug 2020'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:08
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:10
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:57:46
User closed query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:33:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:01:36
Query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. ' answered with 'Site is not going to be leaving these queries open until end date is available. We are being flagged for having all these queries. Most of these may not even have end dates by study closure. ' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 20:24:23
User opened query 'PV Query: Please provide the event end date, when available. Please leave query open until end date is available. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 11:49:55
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 20:32:51
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'SUBJECT HAS NOT RECIEVED RESULTS YET. ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:54:03
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Aug 2020 12:50:39
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:19
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:23
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:28
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:30
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:32
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:34
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:40
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:41
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:46
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:48
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:50
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:52
User entered '1'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:47:59
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:48:01
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:48:03
User entered 'None (NONE)'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:02:36
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		10 Nov 2020 20:29:00
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 20:29:00
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4) System	10 Nov 2020 20:26:16
User entered '1'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

US3412184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:03:07
Query 'per ETRTR: When determined, please ensure to register any concomitant medication or procedure for this SAE, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:43:54
User opened query 'per ETRTR: When determined, please ensure to register any concomitant medication or procedure for this SAE, thanks.' (Site from CRA).	(b) (4), (b) (6)	19 Aug 2020 21:29:28
User entered '0'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 23:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:02:36
User closed query 'Please consider adding MRI on 17 Sep 2020 to Concomitant Procedures page' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:01:46
Query 'Please consider adding MRI on 17 Sep 2020 to Concomitant Procedures page' answered with 'MRI has been added under con procedures. ' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 20:28:48
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 20:26:16
User opened query 'Please consider adding MRI on 17 Sep 2020 to Concomitant Procedures page' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:02:59
User entered '0'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:57:23
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:33:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:02:21
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Site is not going to be leaving these queries open until end date is available. We are being flagged for having all these queries. Most of these may not even have end dates by study closure. ' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 20:24:40
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Aug 2020 12:50:55
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 23:46:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 23:46:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Steven Anderson (b) (4)	17 Aug 2020 23:46:59
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 23:46:23
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:03:20
User entered empty.	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Steven Anderson (b) (4)	24 Nov 2020 21:52:07
User entered 'SUBJECT CONTACTED FOR TELEPHONE VISIT @ 17:30. SHE NOTES SHE HAD A MAMOGRAM AND BIOPSY LAST WEEK OF HER RIGHT BREAST ON 12-AUG-2020. SHE WAS INFORMED THAT THEY FOUND STAGE 0 BREAST CANCER (NO INVOLVEMENT OF LYMPH NODES). BONE MINERAL DENSITY SCAN IS IN THE NORMAL RANGE MRI BREAST BILATERAL W WO BREAS-ICD-10-CM. D05.11- INTRADUCTAL CARCINOMA IN SITU OF RIGHT BREAST-ICD-10-CM THE CLIP PLACED AT TIME OF BIOPSY IS PRESENT IN THE POSTERIOR RETROAREOLAR/6:00 PART OF THE RIGHT BREAST. WITH THE PATIENT PRONE, THIS IS 9.5 CM POSTERIOR TO THE NIPPLE. THERE IS A MINIMAL ILL-DEFINES 5MM SIZE AREA OF ENHANCEMENT AT THE LEVEL OF THE CLIP. NO EVIDENCE OF MULTICENTRIC OR MULTIFOCAL ABNORMALITY. NO SUSPICIOUS ENHANCEMENT PRESENT ELSEWHERE IN EITHER BREAST. NO EVIDENCE OF AXILLARY OR INTERNAL MAMMARY CHAIN ADENOPATHY. KNOWN BIOPSY PROVEN MALIGNANCY. NO EVIDENCE OF MULTICENTRIC OR MULTIFOCAL ABNORMALITY. MINIMAL POSTBIOPSY CHANGES ON THE RIGHT ARE PRESENT Subject is taking part in another pharmaceutical trial for arimidex for breast cancer. This was approved by the medical monitor that subject can continue with follow up and site will document the protocol deviation.' reason for change: Data Entry Error	Steven Anderson (b) (4)	24 Nov 2020 21:52:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:57:30
User closed query 'PV Query: Please consider removing medical history of right breast ductal carcinoma in situ (ER positive) as it has been reported as a SAE.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:33:18
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:33:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:02:36
User closed query 'please update narrative with MRI on 17 Sep 2020 and action/plan for treatment' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:02:11
Query 'please update narrative with MRI on 17 Sep 2020 and action/plan for treatment' answered with 'there has been no treatment plan as of yet. site is trying to follow up with patient to review plan of action.' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 20:28:12
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'there has been no treatment plan as of yet. site is trying to follow up with patient to review plan of action.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 20:28:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider removing medical history of right breast ductal carcinoma in situ (ER positive) as it has been reported as a SAE.' answered with 'medical history form has been updated.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 20:26:59
User opened query 'please update narrative with MRI on 17 Sep 2020 and action/plan for treatment' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:04:06
User closed query 'Please update narrative' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:04:06
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 14:00:28
User opened query 'PV Query: Please consider removing medical history of right breast ductal carcinoma in situ (ER positive) as it has been reported as a SAE.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:58:57
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:58:45
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 13:58:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 14:40:46
User closed query 'PV Query: Please provide records from oncology consultation appointment, when available, with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 14:40:34
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 14:40:20
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including MRI). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 14:40:14
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including MRI). Please include units and reference ranges if applicable.' answered with 'all results were input from procedures in site narrative along with con procedures updated as well' (Site from Safety).	Steven Anderson (b) (4)	21 Oct 2020 19:41:42
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'Subject has not started any new medications. site will follow up with subject at the next phone call to see if status has changed.' (Site from Safety).	Steven Anderson (b) (4)	21 Oct 2020 19:29:25

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide records from oncology consultation appointment, when available, with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records are being sent to fax number provided' (Site from Safety).	Steven Anderson (b) (4)	(b) (4) 21 Oct 2020 14:44:33
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no treatment has been provided as of yet.' (Site from Safety).	Steven Anderson (b) (4)	(b) (4) 21 Oct 2020 13:37:56
Query 'Please update narrative' answered with 'narrative has been updated with results from any procedure subject obtained.' (Site from CRA).	Steven Anderson (b) (4)	(b) (4) 21 Oct 2020 13:37:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED FOR TELEPHONE VISIT @ 17:30. SHE NOTES SHE HAD A MAMMOGRAM AND BIOPSY LAST WEEK OF HER RIGHT BREAST ON 12-AUG-2020. SHE WAS INFORMED THAT THEY FOUND STAGE 0 BREAST CANCER (NO INVOLVEMENT OF LYMPH NODES). Bone Mineral Density scan is in the normal range MRI Breast bilateral w wo breas-ICD-10-CM. D05.11- intraductal carcinoma in situ of right breast-ICD-10-CM The clip placed at time of biopsy is present in the posterior retroareolar/6:00 part of the right breast. With the patient prone, this is 9.5 cm posterior to the nipple. There is a minimal ill-defines 5mm size area of enhancement at the level of the clip. No evidence of multicentric or multifocal abnormality. no suspicious enhancement present elsewhere in either breast. No evidence of axillary or internal mammary chain adenopathy. known biopsy proven malignancy. No evidence of multicentric or multifocal abnormality. Minimal postbiopsy changes on the right are present' reason for change: Data Entry Error	Steven Anderson (b) (4)	21 Oct 2020 13:36:47
User opened query 'PV Query: Please provide records from oncology consultation appointment, when available, with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 13:49:48
Query 'PV Query: Please provide records from oncology consultation appointment when available.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 13:49:33
User opened query 'Please update narrative' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 19:02:46
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Aug 2020 12:53:29

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide records from oncology consultation appointment when available.' (Site from Safety).	(b) (4), (b) (6)	20 Aug 2020 12:51:41
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Aug 2020 12:51:34
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including MRI). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Aug 2020 12:51:12
User entered 'Subject COnfirmed for telephone visit @ 17:30. She notes she had a mamogram and biopsy last week of her right breast on 12-Aug-2020. SHE was informed that they found stage 0 breast cancer (no involvement of lymph nodes). to get an MRI next week to gather further detail on 26-Aug-2020. Subject saw an oncologist- was told radiation is a possibility. Will follow up. Records are pending.'	Steven Anderson (b) (4)	17 Aug 2020 23:46:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '1'	System	21 Aug 2020 03:13:21
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:13:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 03:13:21
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:13:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:13:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:22:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:05:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:12:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:12:51
Data point term sent to Coder	System	08 Sep 2020 14:07:43
User entered 'ADVIL'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'No (N)'	Myelene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'OSTEOARTHRITIS OF KNEE'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:36:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:36:56
User entered '200' reason for change: Data Entry Error	Melissa Fuson (b) (4)	15 Oct 2020 12:36:56
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:06:46
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:36:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:36:56
User entered 'mg (mg)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	15 Oct 2020 12:36:56
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:06:46
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:47:53
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'verified source and updated' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	15 Oct 2020 12:37:15
User entered 'UN UNK 2010' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	15 Oct 2020 12:36:56
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 07:58:06
User entered 'UN UNK 2000'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered '0'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 14:06:46

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:08:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:08:58
Data point term sent to Coder	System	08 Sep 2020 14:07:46
User entered 'MULTIVITAMIN'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:21:46
Query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' answered with 'updated' (Site from DM).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:46:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:46:16
User opened query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:42:46
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'GENERAL HEALTH'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:38:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:38:29
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4)	15 Oct 2020 12:38:29
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Sep 2020 14:07:34
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:38:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:38:29
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	15 Oct 2020 12:38:29
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	08 Sep 2020 14:07:34
	Mylene Asmar-Rios	08 Sep 2020 14:07:34
	(b) (4)	

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'UN UNK 2000'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered '0'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 14:07:34

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL, PRODUCTSYNONYM: OMEGA 3 [FISH OIL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:25:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:25:48
Data point term sent to Coder	System	08 Sep 2020 14:08:47
User entered 'OMEGA 3 (FISH OIL)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:21:51
Query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' answered with 'updated' (Site from DM).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:46:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:46:40
User opened query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:43:14
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'GENERAL HEALTH'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:39:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:39:11
User entered '1000' reason for change: Data Entry Error	Melissa Fuson (b) (4)	15 Oct 2020 12:39:11
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:08:30
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:39:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:39:11
User entered 'mg (mg)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	15 Oct 2020 12:39:11
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:08:30
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'UN UNK 2000'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered '0'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 14:08:30

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:10:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:10:48
Data point term sent to Coder	System	08 Sep 2020 14:09:50
User entered 'VITAMIN D3'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:21:57
Query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' answered with 'updated' (Site from DM).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:47:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:47:02
User opened query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:43:32
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'GENERAL HEALTH'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:39:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:39:31
User entered '1000' reason for change: Data Entry Error	Melissa Fuson (b) (4)	15 Oct 2020 12:39:31
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:09:06
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:39:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:39:31
User entered 'IU (IU)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	15 Oct 2020 12:39:31
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 14:09:06
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'UN UNK 2000'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered '0'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered empty.	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:10:57
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 14:09:06

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:22:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	21 Oct 2020 19:29:36
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:22
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	08 Sep 2020 14:09:16

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:22:31

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered '12 Aug 2020'	Steven Anderson (b) (4)	21 Oct 2020 19:35:04

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:22:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered 'Mam sterotactic loc breast biopsy right'	Steven Anderson (b) (4)	21 Oct 2020 19:35:04

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4)	21 Oct 2020 19:35:04

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:22:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered empty.	Steven Anderson (b) (4)	21 Oct 2020 19:35:04

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:22:31

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered '16 Sep 2020'	Steven Anderson (b) (4)	21 Oct 2020 19:38:30
	(b) (4)	

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:22:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered 'DX Bone density Axial Skeleton'	Steven Anderson (b) (4)	21 Oct 2020 19:38:30

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4)	21 Oct 2020 19:38:30

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:22:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered empty.	Steven Anderson (b) (4)	21 Oct 2020 19:38:30

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:22:31

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered '17 Sep 2020'	Steven Anderson (b) (4)	21 Oct 2020 19:39:28
	(b) (4)	

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:22:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered 'MRI Breast bilateral w wo contrast w CAD'	Steven Anderson (b) (4)	21 Oct 2020 19:39:28

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4)	21 Oct 2020 19:39:28

US3412184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 09:22:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:03:02
User entered empty.	Steven Anderson (b) (4)	21 Oct 2020 19:39:28

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'USA-US061-2020-MRNA-1273-P301000002'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered 'Gregory'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered 'Gottschlich'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered '4260 Glendale Milford Road'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:47:33
User entered empty.	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered empty.	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered '45242'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:43:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Nov 2020 15:33:50
User entered '2'	System	22 Oct 2020 14:00:54
User entered '1'	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'USA-US061-2020-MRNA-1273-P301000002'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered 'Gregory'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered 'Gottschlich'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered '4260 Glendale Milford Road'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:47:33
User entered empty.	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered empty.	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered '45242'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:43:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Nov 2020 15:33:50
User entered '2'	System	22 Oct 2020 14:00:54
User entered '1'	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:22:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
User entered '18/Aug/2020 09:46'	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:22:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered '1'	(b) (4), (b) (6)	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'USA-US061-2020-MRNA-1273-P301000002'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered 'Gregory'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered 'Gottschlich'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered '4260 Glendale Milford Road'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:47:33
User entered empty.	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered empty.	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered '45242'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:43:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Nov 2020 15:33:50
User entered '2'	System	22 Oct 2020 14:00:54
User entered '1'	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:22:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
User entered '22/Oct/2020 10:00'	System	22 Oct 2020 14:00:54

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:22:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:33:38
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
User entered '1'	(b) (4), (b) (6)	22 Oct 2020 14:00:54

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'USA-US061-2020-MRNA-1273-P301000002'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'No (N)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:45:43
User entered 'Yes (Y)'	System	18 Aug 2020 13:40:20

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered 'Gregory'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered 'Gottschlich'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered '4260 Glendale Milford Road'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:47:33
User entered empty.	Steven Anderson (b) (4)	18 Aug 2020 22:35:40
	(b) (4)	

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered empty.	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
User entered '45242'	Steven Anderson (b) (4) (b) (4)	18 Aug 2020 22:35:40

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:46:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 14:00:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:43:12
User entered 'US' (non-conformant).	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Nov 2020 15:33:50
User entered '2'	System	22 Oct 2020 14:00:54
User entered '1'	System	18 Aug 2020 13:46:01

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:22:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '11/Nov/2020 15:33'	System	11 Nov 2020 15:33:50

US3412184

Folder: SAE USA-US061-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:22:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 15:33:50